MAR 9 2006

510(k) Summary
Emit® 2000 Tacrolimus Calibrators

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K06037

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Dade Behring Inc. 20400 Mariani Ave. Cupertino, CA 95014
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	Feb. 7, 2006

2. Device Name / Classification

Emit® 2000 Tacrolimus Calibrators / Class II

3. Identification of the Predicate Device

Abbott IMx® Tacrolimus II Calibrators, P970007
(Note: Tacrolimus test systems have been reclassified into Class II since the predicate was approved.)

4. Device Description

The Emit® 2000 Tacrolimus Calibrators are intended for use as a reference in measuring tacrolimus in human whole blood using the Emit® 2000 Tacrolimus Assay. The calibrators contain tacrolimus in preserved whole blood hemolysate. The calibrator kit consists of one vial of each calibrator level with target concentrations of 0, 2.5, 5, 10, 20, and 30 ng/mL of tacrolimus.

5. Device Intended Use

The Emit® 2000 Tacrolimus Calibrators are intended for use as a reference in measuring tacrolimus in human whole blood using the Emit® 2000 Tacrolimus Assay.

6. Medical device to which equivalence is claimed and comparison information

The Emit® 2000 Tacrolimus Calibrators are substantially equivalent in intended use and technological characteristics to the Abbott IMx® Tacrolimus II Calibrators. Both devices are calibrators intended for use as a reference in measuring tacrolimus with their respective assays. The Emit® 2000 Tacrolimus Calibrators consist of 6 calibrator levels – 0, 2,5, 5, 10, 20 and 30 ng/mL – in whole blood hemolysate. The Abbott IMx® Tacrolimus II Calibrators consist of 6 calibrator levels – 0, 3, 6, 12, 20, and 30 ng/mL – in whole blood hemolysate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 9 2006

Ms. Yuk-Ting Lewis
Regulatory Affairs & Compliance Manager
Dade Behring Inc.
Glasgow Business Community
P.O. Box 6101, Building 500, M/S 514
Newark, DE 19714-6101

Re: k060371
Trade/Device Name: Emit® 2000 Tacrolimus Calibrators
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: February 7, 2006
Received: February 13, 2006

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060371

Device Name: Emit® 2000 Tacrolimus Calibrators

Indications For Use:

The Emit® 2000 Tacrolimus Calibrators are intended for use as a reference in measuring tacrolimus in human whole blood using the Emit® 2000 Tacrolimus Assay.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060371